Contact Network Transmission Modeling of Healthcare Associated Infections: Identifying Effective Symptom-Based Markers for COVID-19 Transmission
Study Protocol

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Principal Investigator: Alberto Maria Segre, PhD

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Protocol Version and Amendment Tracking

Study Title: Contact Network Transmission Modeling of Healthcare Associated Infections: Identifying Effective Symptom-Based Markers for COVID-19 Transmission

Version Number/Amendment	Approval Date
Original Protocol, Version 1.0	07/23/2020

Protocol Synopsis

Protocol Title	Contact Network Transmission Modeling of Healthcare Associated Infections: Identifying Effective Symptom-Based Markers for COVID-19 Transmission
Main Criteria for Inclusion	Tested positive for COVID-19
Study Objective	To further the understanding of COVID-19 symptom development throughout the infection period, as well as how those symptoms vary at different points of the day.

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1. Introduction

1.1 Background

One important approach for decreasing COVID-19 transmission in healthcare settings is to prevent healthcare professionals from working while ill. Currently, facilities are asking screening questions and measuring temperatures to help identify symptomatic healthcare professionals and exclude them from providing patient care. Simulations can be used to inform the effectiveness of different screening approaches, but the results of these simulations depend upon the effectiveness of the intervention, e.g., the ability to identify healthcare professionals on their way to work, or to study the impact of healthcare professionals returning to work too early. Thus, simulations must necessarily depend upon realistic disease parameters: for example, it is suspected that a non-trivial proportion of patients with COVID-19 may be asymptomatic or have minimal symptoms, but the relative size of the asymptomatic subpopulation is unknown.

The plan for this study is to develop a method for granular measurement of twice-daily symptoms from healthcare professionals and other research subjects of similar ages. After being diagnosed, the goal is to determine what symptoms participants have and how long they have had them. This will be done using a previously developed bidirectional texting platform to query participants about symptoms at least twice a day for ten days post diagnosis. Participants will be asked about subjective symptoms, including fevers, chills, cough, shortness of breath, fatigue, gastrointestinal symptoms, etc. They will also take their temperature twice daily during the recovery period, which will help determine the effectiveness of screening based on symptoms and/or thermometer readings.

2. Objective and Aim

2.1 Objective

The goal of this trial is to further the understanding of COVID-19 symptom development throughout the infection period, as well as how those symptoms vary at different points of the day.

3. Subject Inclusion/Exclusion Criteria

3.1 Inclusion Criteria

- Age 18 – 100 years
- Able to speak and read English
- Have tested positive for COVID-19

3.3 Exclusion Criteria

- prisoner status
- unable to provide own written informed consent

4. Study Design

4.1 Overview

In this study, COVID-19 positive patients will be added to a bidirectional texting program to receive daily surveys about their symptoms with the infection. This data will further the understanding of COVID-19 symptom development throughout the infection period, as well as how those symptoms vary at different points of the day. This study will be a single cohort, observational study of COVID-19 patients.

4.2 Recruitment/Screening Procedures

The research team will identify potentially eligible subjects by screening the COVID-19 Positive Results for Research report that is created in Epic. When a potentially eligible subject is identified, they will be contacted using the email address available in Epic. The potentially eligible subject will be sent an email with screening questions to determine their full eligibility (https://redcap.link/pgpqjs7n). If they are fully eligible, they will be directed to a REDCap informed consent document for them to electronically sign and return to the team.

If participants do not respond to the initial email, they will be sent 1 additional email to see if they are interested in the study. If they still do not respond, they will not be contacted further.

We will minimize coercion by telling them that their participation in the study is completely voluntary and will not have any impact on their treatment. Since the consent process takes place remotely, they will easily be able to read the study information and not complete the form, if they wish.

4.3 Visit Procedures

We will collect the following data from the patient's medical record: date of birth, date of COVID test, type of COVID test, and COVID test number.

Immediately after the participant completes the online REDCap consent form, they will be

directed to the baseline survey. The baseline survey asks for the participant's cell phone number so that we can send them the twice daily survey, the time in the morning they wish to receive text messages, the time in the evening they wish to receive text messages, their mailing address for the compensation check, sex assigned at birth, if they are pregnant (if female), race, ethnicity, if they have any of a list of health conditions that have been shown to be related to worse COVID outcomes, if they are a smoker, and if they have a thermometer that they are able to use for the study. If they do not have a thermometer, we will drop one off outside their home so that they have one to use for the study.

Once that is complete, they will be entered into our bi-directional text messaging platform and sent 1 message every morning and 1 message every evening. These messages will remind them to measure their temperature and will ask about any current COVID-19 symptoms that they are experiencing. They will be sent text message reminders for 10 days.

4.4 Statistical Analysis Plan

We will calculate summary statistics for participants' demographic characteristics (e.g., mean age, counts of comorbidities, percentage of females). We will also determine the progression of temperatures and symptoms over time. For example, we will determine when fevers occur, how many days fevers last, what symptoms are present, and how long symptoms last.

This is a descriptive pilot study, so no power analysis was performed or required. 500 was chosen as the number to enroll because we need a large sample of participants to learn about the various symptoms of this condition. Also, due to the remote nature of the study and the fact that the population is already known to be ill, we expect a large number of dropouts during the course of the study.